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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,650	07/31/2006	Kay Teraoka	DYNG/P026064	9361
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WALL & TONG, LLP 595 SHREWSBURY AVE. SHREWSBURY, NJ 07702				
EXAMINER				
KETTER, JAMES S				
ART UNIT		PAPER NUMBER		
1636				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/579,650

## Applicant(s)

TERAOKA ET AL.

## Examiner

James S. Ketter

## Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/02)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_
- Paper No(s)/Mail Date 1/22/07

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Starling et al. (A, newly cited).

Claim 1 is drawn to a cell picking tool which is a molded body with a concave structure capable of picking a cell sheet which has been two-dimensionally cultured in a culture container while keeping the sheet form (while keeping the cells in a state of aggregation) without using a cell dispersant, characterized in that the concave structure is made of a material having a cell adhesive property, the area of the opening portion of the concave structure ranges from 100 to  $9 \times 10^6$  micron<sup>2</sup>, and, when the opening portion of the concave structure and the cell sheet are brought into contact with each other, the opening portion of the concave structure and the cell sheet adhere to each other. The recited area of the opening portion of the concave structure thus ranges from approximately 10 to 3000 microns in diameter. Claim 2 specifies within claim 1 that the molded body comprises a calcium phosphate ceramic. Claim 3 specifies within claim 1 that the molded body is in a shape with a cross section having an aspect ratio (long axis/short axis) ranging from 1.005 to 5, and when it is placed on a flat surface, apart or the whole of an opening portion of a pore, a through hole or a dimple faces downward. Claim 4 specifies within claim 1 that the molded body is a molded body mixture of one type or two or more types selected from the group consisting of a spherical shape, a bead shape, a block shape, a plate shape, a polyhedral shape, a chestnut bur-like shape, a dendritic shape and a protruding shape with a size

ranging from  $5 \times 10^{-4}$  to  $1 \times 10^3 \text{ mm}^3$ . Claim 5 specifies within claim 1 that the molded body has one type or two or more types of structures selected from the group consisting of a pore, a through hole, a dimple, a slit, a joint formed by joining portions of protrusions, a surface adsorptive protein, a hydrophilic-treated surface, apolymer coat and an oxide film. Claim 6 is drawn to a molded body/cell complex in which cells are attached to the opening portion of the concave structure of the molded body according to claim 1. Claim 7 is drawn to a two-dimensionally or three-dimensionally accumulated matter of the molded body/cell complexes according to claim 6. Claim 8 is drawn to a cell handling method, characterized in that by placing the cell picking tool according to claim 1 in a container (cell collection site) in which cells grow, cells are attached to the molded body and allowed to grow (passive cell collection), whereby the cells are handled together with the cell picking tool.

Starling et al. teaches, e.g., at Figures 1-3, a particle with an aperture. At column 4, lines 28-53, it is taught that the particles may be used without interconnection to support cell growth, and that the aperture serves as a site for cell ingrowth. At the paragraph bridging columns 7 and 8, it is taught that the particles may be made of hydroxyapatite or glass, among a number of other biologically-compatible materials. At the first full paragraph at column 8, it is taught that the length of the particle "is less than about 3 millimeters, preferably between about 225 and 2000 microns, more preferably between about 300 and 1000 microns, and most preferably about 700 microns. The diameter of the particle, i.e. the diameter of the outer cylindrical wall of the particle is less than about 3 millimeters and preferably between about 425 and 2000 microns, more preferably between about 500 and 1000 microns, and most preferably about 925 microns. The cylindrical particle can have a length which is greater than, equal to or less than the diameter of

the particle. The ratio of the length to the outside diameter is preferably between about 0.5 and 1.5". At the subsequent paragraph it is taught that the aperture may be between about 500 and 1000 microns, and preferably less than about 500 microns in diameter, more preferably between 150 and 400 microns in diameter, most preferably about 225 to 300 microns in diameter. The paragraph bridging columns 15 and 16, and also Example 5, teaches growth of cells on and into the aperture of the particles.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, and therefore dependent claims 2-8, the parenthetical phrase at lines 4 and 5, "(while keeping the cells in a state of aggregation)" is not identical in scope with the clause that precedes it ("while keeping the sheet form"), and as such, the metes and bounds of the claims are unclear.

Claim 4 recites "a bead shape", "a chestnut bur-like shape", "a dendritic shape" and "a protruding shape". However, these are not geometrically defined shapes as are the others in the claim, but rather refer to objects of highly variable and undefined contours and dimensions. As such, the metes and bounds of the claim are unclear.

Claim 5 recites “one type or two or more types of structures”. However, the use of “or” twice is not in accordance with the principles of grammar, and as such, it renders the meaning of the claim confusing.

Claim 7 recites the term “accumulated matter”. However, it is not clear to what the term refers, i.e., does it refer to: a plurality of the body/cell complexes; an aggregation of a plurality of the cell/body complexes; to a by-product of the cells or the cell/body complexes; or to some other structure? As now drafted, the claim is thus of uncertain metes and bounds.

Claim 8 does not make clear what the actual, active process steps of the method are. Applicants should redraft the claim to clarify.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK  
26 February 2009

/James S. Ketter/  
Primary Examiner, Art Unit 1636